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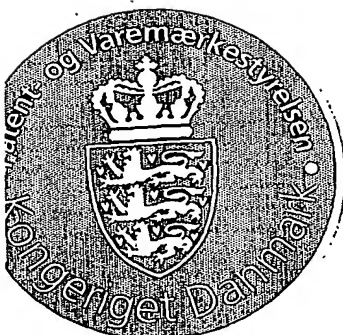
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A blood pressure measuring implement.

- 5 The invention concerns apparatus for measuring blood pressure comprising a generally tubular constrictable sleeve or cuff for the upper arm of a person, a source for fluid pressure, means for measuring static pressure, and microphone means arranged in proximity to an artery.
- 10 Modern blood pressure measurements have long traditions and fall into two distinct types. Both use the constriction of an artery to such a degree that blood flow is stopped and then allowed to flow while a signal derived from the blood pressure is monitored. The constriction occurs by means of a cuff surrounding a limb (in most cases an upper arm or a wrist). The cuff has a non-stretchable fabric on the outside
- 15 enclosing an elongate bladder surrounding a large part of the limb periphery. The bladder is pressurised by means of air, and the air pressure is monitored. The Korotkoff method depends on listening to sounds in the artery downstream of the constriction as blood begins to flow, and to read the pressure when certain sounds related to the heartbeat are heard and again when sounds begin to disappear.
- 20 Traditionally, the listening has occurred by means of a stethoscope, the chestpiece of which is held against the skin in proximity to the artery downstream from the occlusion, frequently supported against the edge of the cuff.
- The above process of measuring blood pressure is perceived as a slow process and one which requires skill. This is due to the manipulation, requiring two hands,
- 25 involved in fitting the cuff, and the need for precise placement of the stethoscope chestpiece. The pumping and release of air are perceived as the least time consuming, particularly because they pertain to the actual measurement. Modern measurement methods use automatic pumping and release and electronic
- 30 microphone pickup of the Korotkoff sounds and possibly some signal processing aids in distinguishing between the various types of sound.

US 4,337,778 describes an attempt to reduce the entanglement of air tube and microphone lead in connection with the wrapping and unwrapping of the cuff, in

that the Korotkoff sounds are picked up by means of a microphone inside the inflatable bladder. However, the patent does not attempt to solve the fundamental time-consuming problem of the wrapping and unwrapping.

5 In US 5,560,365 it is described how the provision of a partially stretchable cuff may reduce friction noises in case the blood pressure measurement is performed on a non-stationary limb. It improves the signal to be analysed, but it does not solve the problem of fitting the cuff.

10 In US 4,248,242 it is described how a blood pressure apparatus may be semi-automated by means of a sequential switch and hand pump arranged on apparatus integrated with the cuff. The cuff itself still has to be threaded on the arm. A sensor is provided for picking-up the Korotkoff sounds but there is no indication of the manner in which it is fitted to the apparatus.

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In US 4,005,701 it is described how the signal-to-noise ratio may be improved for the microphone sensing the Korotkoff sounds in that a second microphone is provided to pick up extraneous noises, and signal processing is provided to enable discrimination of the Korotkoff sounds. The fitting of the cuff is traditional, and
20 only the skill needed for placing the microphone/chestpiece is reduced by this disclosure.

According to the invention the above deficiencies are avoided, in that the cuff is partly enclosed in two elongate and essentially concave shell parts which are
25 openable against a restoring force. There is a distinct advantage to using a stiff shell for enclosing the inflatable cuff, rather than the traditional woven strap, because the forces between the cuff and the limb (upper arm) are more evenly distributed and so facilitate a stable and repeatable occlusion of the artery.

30 According to an advantageous embodiment the shells are fitted on a hinge connected to handle parts operable by one hand. This in effect means that correct placement of the implement is possible using one hand only, whereby a person may use the implement on himself.

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According to a further advantageous embodiment the hinge is a continuous resilient part joining the shell parts. It is important that the shells fits closely to the tissue when the implement is fitted, and the handles act against the force of such a resilient part.

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According to a further advantageous embodiment the shell parts are integral with the hinge part, forming one continuous sheet of material. This means that the implement may be manufactured in one piece which is given its proper shape during manufacture.

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According to a further advantageous embodiment the continuous sheet of material assumes a generally frusto-conical shape. This "pre-distortion" of the shape of the implement is most practical in connection with well-developed muscles in the upper arm. However, it has been determined that in connection with the shell-type construction according to the invention the frusto-conical shape of the implement has a larger range of adaptation to biometrical measurements than a cylindrical type.

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According to a further advantageous embodiment an inelastic strap attached to one shell part is provided to close the gap between the shell parts. The use of a strap is known per se from traditional cuffs, however, according to the invention its action is more consistent because it attaches the shell parts.

20

According to a further advantageous embodiment the strap is provided with means locking to the other shell part. Such means would be of a quick-release type.

25

According to a further advantageous embodiment mechanical actuating means fitted in proximity to the hinge part compress one shell part towards the other during measurement. In case the implement is to be used by persons having too little strength in the actuating hand, the opening of the shell parts by means of the handles may be made to require only a small force. However, in this case some mechanical assistance is required to compress the two shells towards each other prior to fitting a strap and measurement.

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According to a further advantageous embodiment the mechanical actuating means consist of an air cylinder and levers. Air under pressure is available for inflating the air chambers of the cuff, and hence a suitable actuating means for the shell parts would be an air cylinder or another closed shape-changing vessel.

5

According to a further advantageous embodiment the mechanical actuating means consist of strings fitted near the inner side of each shell part and disposed perpendicular to the longitudinal axis of such shell part. This type of actuation is more adapted to electric power, because the strings may be tightened by winding them on a rotating shaft.

10

According to an embodiment of the invention an inflatable cuff forms an inner lining to the shell parts, providing an inflatable main air chamber. With the secure support of the shell parts it is possible to obtain a secure and repeatable inflation, without any distortion of the air chamber that could lead to difficulties in occluding the blood vessels.

15

According to a further advantageous embodiment the strap is provided with air chambers disposed essentially perpendicular to the orientation of the shells and communicating with the main air chamber. This in effect means that an inflatable structure surrounds the whole arm, again providing improved repeatability in inflation.

20

According to a further advantageous embodiment a linear array of microphone elements is disposed on a universal joint type support in one shell part essentially perpendicular to the longitudinal axis of such shell part and near the lower end. It has been determined that the rotational precision required in fitting the implement is much reduced by providing several microphones, because it will at all times be possible to find the microphone which provides the clearest signal.

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According to a further advantageous embodiment the universal joint is emulated by a foam pad. This is an efficient manner to provide a support for the microphone bridge, both from a manufacturing viewpoint and because the resilience of the foam

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pad may be adjusted in correspondence to the length of the bridge, thickness of the microphone elements, etc.

5 According to a further advantageous embodiment the universal joint is emulated by means of a separate air chamber fitted between the cuff and the microphone array. This means that the contact pressure of the microphone bridge may be adjusted during measurement, if required.

10 According to a further advantageous embodiment signal selection means of the diversity type are used to select the microphone that provides the best signal-to-noise ratio. Rather than averaging the output of the linear array of microphones it is much more efficient to select the microphone which at the same time receives the strongest signal but also the least amount of extraneous noise.

15 According to a further advantageous embodiment the amount of overlap between the strap and the shell is used as a circumference measure for automatically correcting the reading of blood pressure. It is well known that for a constant circumference of the cuff fitted snugly to a limb, the precision to which the systolic and diastolic pressures are given depends on the axial dimension of the cuff. The length of the
20 implement according to the present invention being constant and precise, due to the stiffness of the shell, knowledge of the circumference enables a suitable correction to be applied to the reading. The absolute value of the circumference is equal to the circumference of the cuff plus the contribution of the flap. The correction is performed during the signal processing in dependence of the overlap signal from the
25 strap. The skilled person will choose any of several technologies available for this kind of relative position measurement. Hence the need for several sizes of cuffs known from traditional blood pressure measuring setups is reduced.

30 The invention will be more fully described in the following with reference to the drawing, in which:

Fig. 1 shows a first cross section through one embodiment of the invention fitted to a limb,

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Fig. 2 shows a second cross section, further along the limb,

Fig. 3 shows a third cross section, still further along the limb,

5 Fig. 4 shows another embodiment of the invention, seen from the inside, and

Fig. 5 shows signal processing means for selecting a signal with a good signal-to-noise ratio.

- 10 In Fig. 1 there is shown a cross section through a limb around which the inventive implement is fitted. Purely by way of example this is to be considered as an upper left arm extended horizontally forwards with respect to a vertical torso. The arm 1, the bone 2, an artery 3 and a vein 4 are indicated. The arm 1 is enclosed in a shell-like structure consisting of an upper part 5 and a lower part 6, connected by a part 7.
- 15 The parts are made of a material which is pliable around the arm but stiff in its longitudinal direction. To the inside of parts 5, 6, 7 is fitted an inflatable structure 8 which is able to compress the tissue of the arm 1 around the bone 2, provided the shell-like structure does not increase its outer dimensions.
- 20 In Fig. 2 is shown how the outer dimensions of the shell-like structure are maintained. This is obtained in that a strap or flap 9 is connected between the upper part 5 of the shell-like structure and the corresponding lower part 6. The flap is made in a material which does not extend when put under tension, and so the circumference of the inventive implement is constant. When the inflatable structure
- 25 8 is inflated, the implement tends towards a shape which provides the largest area for a given circumference which is a circle, and the tissue in the arm 1 is compressed to a degree which may occlude the blood vessels 3 and 4. The implement is fitted with two handle-like structures 10 and 11 which when brought towards each other will increase the distance between the parts 5 and 6, provided the flap 9 has not been
- 30 connected. A resilient member 12 is acting on the handle structures 10 and 11, attempting to close the shell-like structure 5, 6.

In practical use one hand may act on the handles 10, 11 to open the shell parts 5, 6 in order to fit the implement on the arm 1; in the example above this would be from the

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right towards the left. The handles 10, 11 are released, the resilient member 12 expands in closing the shell parts 5, 6, and a loose end 13 hanging down from the flap 9 connected to the upper part 5 is gripped from below with the same hand that released the handles and is brought to the right with a pulling motion. The flap 9
5 attaches itself to the lower part 6 by releasable means, such as the fastener type described in US 2,717,437. The inflatable structure 8 is provided by air under pressure, and the blood vessels are occluded when sufficient pressure has built up.

In Fig. 3 the downstream (looking at the flow in an artery) end of the implement is
10 shown in cross section. This end carries a set of microphones for picking-up signals from the flow in the artery 3. Three microphones 14, 15, and 16 are fitted onto a fixture 17 which is mounted on a universal joint type of bearing 18 in order that the fixture may fit closely to the skin in proximity to the artery 3. In a preferred
15 embodiment the universal joint is emulated by a foam pad. One microphone 16 is shown as being closest to the artery, and the signal from this microphone will have the best signal-to-noise ratio of the three. This is in contrast to a construction embodying an elongate microphone, such as that described in US 4,202,348. While
20 this patent does describe how it is ensured that a signal from an artery is picked up for a range of rotational orientations of the cuff holding the microphone, said construction equally collects various noise signals.

The universal joint type bearing 18 may equally be a small air cushion, not necessarily connected to the main inflatable structure.

25 In Fig. 4 is shown a different embodiment of the invention, but for clarity it is shown in a form that it would never assume as a finished product. In this case the two shells 50, 60 and the hinge 70 are made of one sheet of material in which the stiffness is dependent on the direction. It is considerably stiffer in its longitudinal direction than
30 crosswise (around a limb). Such a material may consist of a number of parallel linear structures of increased thickness joined by areas of reduced thickness or may be obtained by corrugation. The upper and lower "shell" parts are pre-formed in a concave shape towards each other, and as in Fig. 2 actuating "handle" parts are able to separate the two "shell" parts, the "hinge" part being equally pre-formed during manufacture. The cross section of this embodiment is similar to Fig. 2, however the

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general outline of the sheet material is such that it will conform to a frusto-conical shape when the implement is applied.

5 In Fig. 4 the "shell" and "hinge" parts 50, 60, 70 are shown "flattened" to the image plane. Furthermore is shown the main air chamber 80 lining the sheet of material as well as supplementary air chambers 81, 82, 83, 84 lining the strap or flap 90 which is used to close the implement in a manner described in connection with Fig. 2. The communicating air chambers may advantageously be made in a flexible weldable poly-urethane sheet material. The position of handles 100 and 110 is indicated by
10 dot-dash lines. It will be obvious to the skilled person that the orientation of the flap 90, i.e. whether the closing movement is upwards or downwards is immaterial to the construction, although it may be important to the user. The closing occurs by means of fasteners 91 co-operating with corresponding fasteners on the outside of the part 60 of the implement. The bridge 170 carrying the microphones 140 is shown
15 adjacent to the air chamber 80.

Upper arms being very different in a population, there may be a need for different sizes of implement, however the implement according to the invention will adapt to many biometrical dimensions, the basic frusto-conical shape being adaptable to
20 create even a cylindrical cuff if required. However, the provision of supplementary air chambers in the flap itself enables a larger range of upper arms to be measured with one and the same implement, than for known cuffs.

The strap 90 and its fastening flap 91 for joining to the outside of the shell 60 are
25 provided with extension measuring means 92, 93 which are able to provide a signal indicating the amount of overlap of the strap when fitted to the limb. This means that a signal related to the circumference of the limb is readily available with high precision for use in correcting the reading of systolic and diastolic pressures. This correction is performed automatically by the implement in the DSP environment
30 assisting the measurement.

In Fig. 5 is shown the principle for selecting the microphone that provides the most significant signal related to the flow in the partly occluded artery 3. A number of microphones 140 are connected to a set of pre-amplifiers 20, and each amplified

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signal is brought to a processing unit 21, which performs digital signal processing by emulating functions comprising high frequency pre-emphasis means, strobing means for selecting each microphone signal, level detection means for each signal, storage means corresponding to each signal for the level of high frequency present,

- 5 comparator means for comparing the level of a newly strobed signal with those stored, and selector means for taking the signal fulfilling the set criteria to a unit 22, in which it is made available to the ear and to a visual indication. In this conjunction electronic transmission of the signal for further processing may also occur. The unit
- 10 criteria by linking the measurements in unit 21 to other measurable quantities having a time function.

PATENT CLAIMS

- 5 1. Apparatus for measuring blood pressure comprising a generally tubular constrictable sleeve or cuff for the upper arm of a person, a source for fluid pressure, means for measuring static pressure, and microphone means arranged in proximity to an artery, characterised in that the cuff is partly enclosed in two elongate and essentially concave shell parts which are openable against a restoring force.
- 10 2. Apparatus according to claim 1, characterised in that the shells are fitted on a hinge connected to handle parts operable by one hand.
- 15 3. Apparatus according to claim 2, characterised in that the hinge is a continuous resilient part joining the shell parts.
4. Apparatus according to claim 3, characterised in that the shell parts are integral with the hinge part, forming one continuous sheet of material.
- 20 5. Apparatus according to claim 4, characterised in that the continuous sheet of material assumes a generally frusto-conical shape.
6. Apparatus according to claim 1, characterised in that an inelastic strap attached to one shell part is provided to close the gap between the shell parts.
- 25 7. Apparatus according to claim 6, characterised in that the strap is provided with means locking to the other shell part.
8. Apparatus according to claim 2, characterised in that mechanical
- 30 actuating means fitted in proximity to the hinge part compress one shell part towards the other during measurement.
9. Apparatus according to claim 8, characterised in that the mechanical actuating means consist of an air cylinder and levers.

10. Apparatus according to claim 8, characterised in that the mechanical actuating means consist of strings fitted near the inner side of each shell part and disposed perpendicular to the longitudinal axis of such shell part.

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11. Apparatus according to claim 1, characterised in that an inflatable cuff forms an inner lining to the shell parts, providing an inflatable main air chamber.

10 12. Apparatus according to claim 6, characterised in that the strap is provided with air chambers disposed essentially perpendicular to the orientation of the shells and communicating with the main air chamber.

15 13. Apparatus according to claim 1, characterised in that a linear array of microphone elements is disposed on a universal joint type support in one shell part essentially perpendicular to the longitudinal axis of such shell part and near the lower end.

20 14. Apparatus according to claim 13, characterised in that the universal joint is emulated by a foam pad.

25 15. Apparatus according to claim 13, characterised in that the universal joint is emulated by means of a separate air chamber fitted between the cuff and the microphone array.

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16. Apparatus according to claim 13, characterised in that signal selection means of the diversity type are used to select the microphone that provides the best signal-to-noise ratio.

30 17. Apparatus according to claim 6, characterised in that the amount of overlap between the strap and the shell is used as a circumference measure for correcting the reading of blood pressure.

ABSTRACT

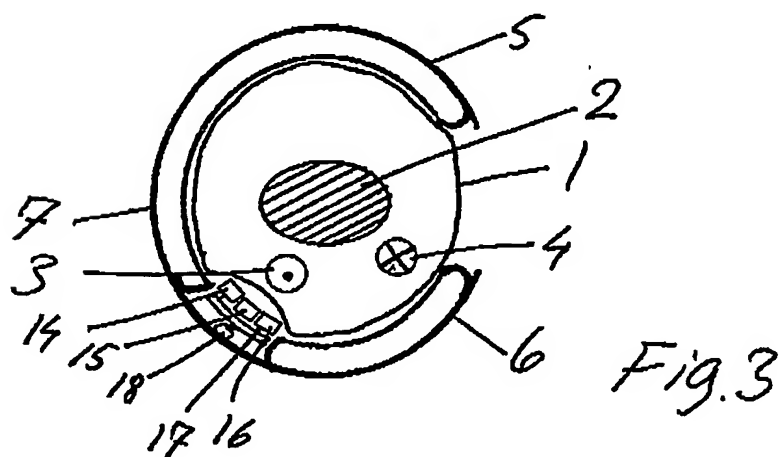
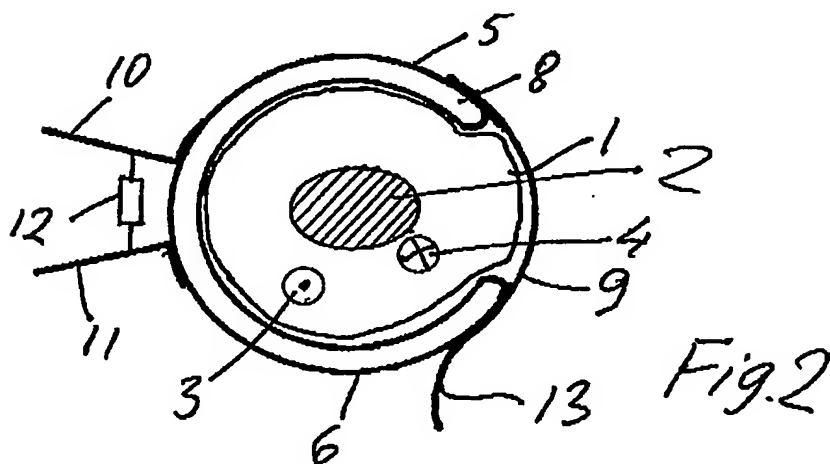
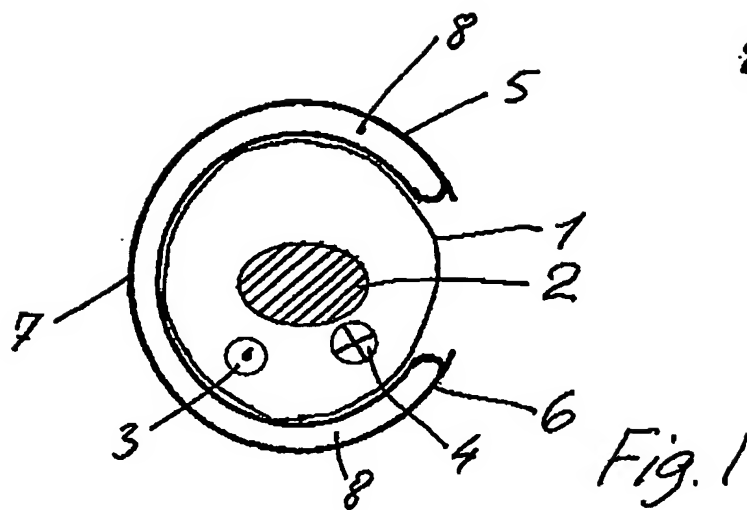
- Traditional cuffs for measuring blood pressure use an air chamber enclosed in a non-stretchable fabric to occlude an artery in a limb when supplied with pressurised air.
- 5 A stethoscope used on the limb is used to monitor blood flow. Application of the cuff is inconvenient and correct placement of the stethoscope chestpiece requires skill. According to the invention blood pressure measurement is facilitated by having the air chamber enclosed in a pre-formed shell-like structure being flexible around the limb and stiff along the limb and by using a linear array of microphones
- 10 to detect the blood flow noises, the best signal from one of the microphones being automatically selected.

(Fig. 4)

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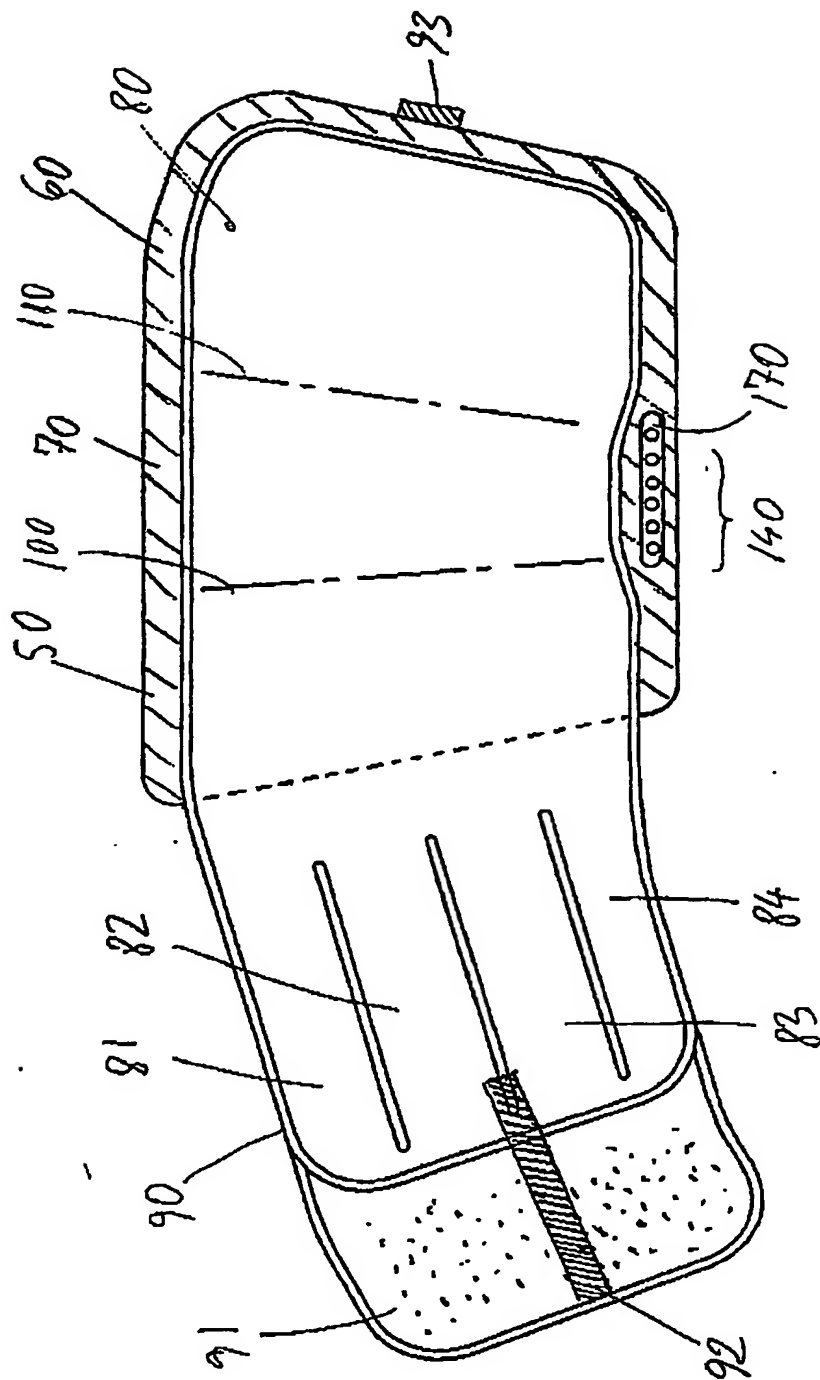


Fig. 4

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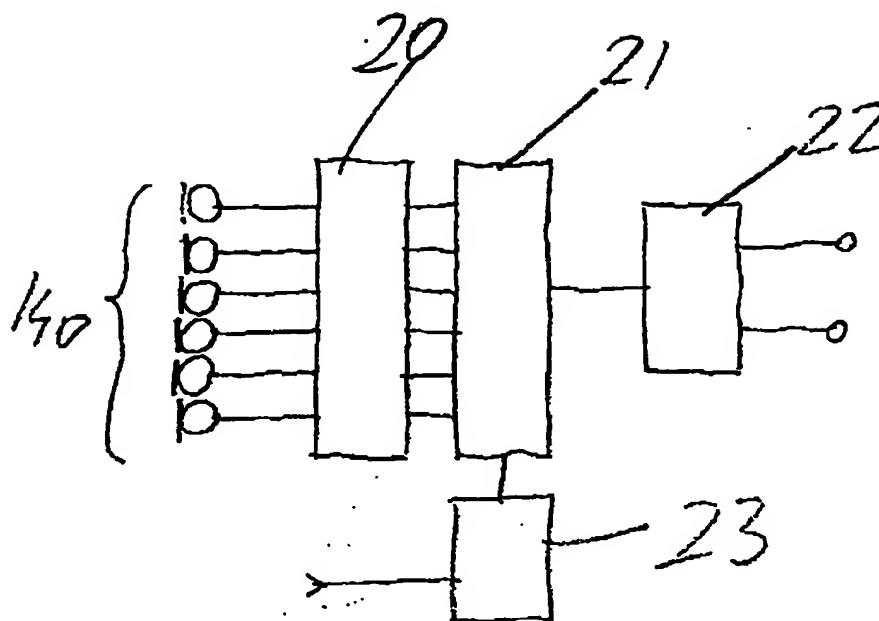


Fig. 5

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